

its relentless march to put more drugs on the market.

With the OxyContin-for-kids decision, the FDA's reckless attitude toward expert advice on drug safety went too far. Children whose brains are not yet fully developed are especially vulnerable to drug dependency and abuse. Yet the agency focused its so-called safety analysis only on concerns about proper dosing, saying that it needed to tell doctors the proper doses for children who needed the drug. That is just plain wrong. We use experts to determine if child car seats are safe, if toothpaste is safe, and if vaccines are safe. We should also use experts to determine if those opioid painkillers are safe for the children in the United States of America.

We need to immediately reform the Food and Drug Administration's opioid approval process if we want to stop this epidemic of prescription drug and heroin addiction in the United States.

When I placed a hold on the nomination of Dr. Califf to head the FDA, I called on the FDA to commit to convening an advisory panel of outside experts for every single opioid approval question it reviewed. Here is how the FDA responded: It responded by committing to convene outside experts but only for opioids that are not abuse-deterrent. Let's be clear. I want everyone in this Chamber to understand this: "Abuse-deterrent opioid" is an oxymoron, like "jumbo shrimp" or "congressional expert." There is no such thing. When we hear the term "abuse-deterrent," think of pills that are tamper-resistant. They are supposed to be difficult to crush or chew or cut open or tamper with. But nothing about abuse-deterrent opioid prevents addiction. There is no such thing as abuse deterrence if you are suffering from addiction and have access to the Internet, where you can find out just how easy these painkillers are to manipulate and abuse. Whether an opioid is abuse-deterrent or not hasn't prevented tens of thousands of people who have had their wisdom teeth extracted or experienced lower back pain from getting addicted to these painkillers.

By refusing to convene advisory committees to reform all of its opioid approval decisions, the FDA continues to ignore outside experts who could help stem the tide of tragic deaths and overdoses plaguing this country.

This all started back with the FDA's 1995 approval of the original OxyContin—the moment in history that is widely recognized as the starting point for the prescription opioid and heroin overdose epidemic in the United States. It started with the FDA. The FDA approved the original version of OxyContin—an extended-release opioid—believing that it "would result in less abuse potential, since the drug

would be absorbed slowly and there would not be an immediate 'rush' or high that would promote abuse." Since then, the claims that opioid is abuse-deterrent have time and again proven oxymoronic.

FDA's own guidelines recognize the inherent contradiction in the term "abuse-deterrent," explaining:

It should be noted that [abuse-deterrent] technologies have not yet been proven successful at deterring the most common form of abuse—swallowing a number of intact capsules or tablets to achieve a feeling of euphoria. Moreover, the fact that a product has abuse-deterrent properties does not mean there is no risk of abuse.

That is from the FDA's own guidelines.

In many cases, the FDA approved so-called abuse-deterrent opioids despite warnings from the medical community about the potential for abuse. And when it wasn't turning a blind eye to the warnings of experts, the FDA simply didn't engage them at all in approval of opioids with abuse-deterrent properties. With numerous approvals of so-called abuse-deterrent opioids since 2010, the agency convened advisory committees for less than half of them.

This issue of abuse deterrence is not a hypothetical concern. The new policy announced by the FDA would not have guaranteed an advisory panel for the OxyContin that is on the market today and being sold in tens of millions of doses or for the other recently approved opioids that have raised serious concerns from public health and medical experts from around our country. The FDA is attempting to set up a system where nothing really changes.

We will not solve the prescription drug crisis with an FDA that operates with business as usual and continues to turn its back to external experts. The FDA needs to welcome outside expert advice and must convene expert advisory panels for all opioid approval decisions, period. Until the FDA makes that commitment, I am going to continue to raise my voice in opposition to the nomination of Dr. Califf.

This is an issue that is central in our country. The terrorist phone call that families in America are afraid of getting is not one from overseas; it is that a member of their family has fallen victim to this prescription drug opioid crisis. It is in every city, every town in our country. We have seen a quadrupling of the number of heroin deaths in our country in the last 13 years, and 80 percent of them started with OxyContin, with Percocet, with one of these prescription drugs.

We need the FDA to do the right thing, and until they do, we need to debate out here on the floor what the responsibilities will be of this new FDA Commissioner, because they have been unwilling to change their policy. Until

they do, these people and communities all across our country are going to be helpless. They are going to be helpless because families think that if a bottle is given to them by an expert, they can trust it. And when their children die—when their children die—they ask themselves the question: Could I have done more? It starts with the FDA. It starts with MEA, mandatory education for physicians. It starts there. If we don't do this, then those families are still going to be having the same result year after year after year.

I thank the majority leader for sitting and hearing my objections. The majority leader and I have had many conversations about this subject, and I know of his deep concern on this issue. I think this is something that can be corrected. I hope it can be corrected. It must be corrected.

I thank the majority leader for staying to hear my presentation.

I yield the floor.

ADJOURNMENT UNTIL 10 A.M. TOMORROW

The PRESIDING OFFICER. The Senate stands adjourned until 10 a.m. tomorrow.

Thereupon, the Senate, at 6:21 p.m., adjourned until Friday, February 12, 2016, at 10 a.m.

NOMINATIONS

Executive nominations received by the Senate:

THE JUDICIARY

ABDUL K. KALLON, OF ALABAMA, TO BE UNITED STATES CIRCUIT JUDGE FOR THE ELEVENTH CIRCUIT, VICE JOEL F. DUBINA, RETIRED.

DEPARTMENT OF EDUCATION

JOHN B. KING, OF NEW YORK, TO BE SECRETARY OF EDUCATION, VICE ARNE DUNCAN.

CONFIRMATIONS

Executive nominations confirmed by the Senate February 11, 2016:

THE JUDICIARY

LEONARD TERRY STRAND, OF SOUTH DAKOTA, TO BE UNITED STATES DISTRICT JUDGE FOR THE NORTHERN DISTRICT OF IOWA.

FOREIGN SERVICE

FOREIGN SERVICE NOMINATION OF CHRISTOPHER NAIRN STEEL.

FOREIGN SERVICE NOMINATIONS BEGINNING WITH CHRISTOPHER ALEXANDER AND ENDING WITH TIPTEN TROIDL, WHICH NOMINATIONS WERE RECEIVED BY THE SENATE AND APPEARED IN THE CONGRESSIONAL RECORD ON SEPTEMBER 10, 2015.

FOREIGN SERVICE NOMINATIONS BEGINNING WITH VIRGINIA LYNN BENNETT AND ENDING WITH SUSAN M. CLEARY, WHICH NOMINATIONS WERE RECEIVED BY THE SENATE AND APPEARED IN THE CONGRESSIONAL RECORD ON JANUARY 19, 2016.

MILLENNIUM CHALLENGE CORPORATION

MORTON H. HALPERIN, OF THE DISTRICT OF COLUMBIA, TO BE A MEMBER OF THE BOARD OF DIRECTORS OF THE MILLENNIUM CHALLENGE CORPORATION FOR A TERM OF TWO YEARS.

MICHAEL O. JOHANNIS, OF NEBRASKA, TO BE A MEMBER OF THE BOARD OF DIRECTORS OF THE MILLENNIUM CHALLENGE CORPORATION FOR A TERM OF THREE YEARS.